FEB 1 4 2013

510(k) Summary
Renovis Surgical Technologies, LLC
A200 Knee System
K120038

January 29, 2013

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	A200 Knee System
Common Name:	Total Knee Prosthesis System
Classification Names:	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer; Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer + additive/metal/polymer + additive
Classification Regulations:	21 CFR 888.3560, Class II
Product Code:	JWH, OIY
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

The A200 Knee System is intended for use in total knee arthroplasty for the following indications:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is intended for cemented use only.

DEVICE DESCRIPTION

The A200 Knee System consists of the following components: Femoral Components – nine (9) sizes in a cruciate-retained (CR) design, each for left and right sides, manufactured from Co-Cr-Mo alloy; Tibial Tray Components – nine (9) sizes, each for the left and right sides, and each in two stem designs, a conical design manufactured from Co-Cr-Mo alloy, and a keeled design manufactured from Ti 6Al 4V alloy; Tibial Insert Components – three (3) footprint sizes, each for the left and right sides, with articulating thicknesses ranging from 10 mm to 20 mm, all in CR designs, in standard and deep dish configurations, manufactured from highly crosslinked ultra-high molecular weight polyethylene with and without vitamin E; Patellar Components – five (5) sizes, in dome design, manufactured from highly crosslinked ultra-high molecular weight polyethylene with and without vitamin E; and A200 Knee Instrumentation including instruments for use with the system components, trial implant components, and general instruments.

The A200 Knee System implants are manufactured from Co-Cr-Mo alloy conforming to ASTM F75, Ti-6Al-4V alloy conforming to ASTM F136, and ultra-high molecular weight polyethylene conforming to ASTM F648 and ASTM F2695. All UHMWPE is crosslinked by gamma irradiation. The metallic implant components (femoral components and tibial tray components) are sterilized by Co^{60} gamma irradiation, and all UHMWPE components are sterilized by ethylene oxide.

EQUIVALENCE TO MARKETED DEVICES

Renovis Surgical Technologies, LLC, submits the following information in this Premarket Notification to demonstrate that for the purposes of FDA's regulation of medical devices, the A200 Knee System is substantially equivalent in indications and design principles to the following legally marketed predicate devices, each of which has been determined by FDA to be substantially equivalent to a legally marketed predicate device:

DePuy Orthopaedics, Inc., DePuy Sigma Knee Femoral Adapter, K060515;

Encore Medical, L.P., Highly Cross-Linked Vitamin E UHMWPE Tibial Insert, K103223;

Biomet Manufacturing Corp., E1™ Tibial Bearings, K100048;

Encore Orthopedics, Inc., Foundation Knee System, K923277;

Zimmer, Inc., MG II Porous Total Knee System, K892800;

U.S. Medical Products, Inc., Consensus Knee System - Primary Knee, K932837; and

Hospital for Special Surgery, Insall-Burstein II, K935080.

The A200 Knee System and the predicate device K060515 are patellofemorotibial knee prosthesis systems, intended for cemented total knee arthroplasty, having the same intended use and similar indications for use.

The A200 Knee System and the predicate device K060515 are made of the same materials, Co-Cr-Mo alloy (femoral components and tibial tray components) and highly crosslinked UHMWPE (tibial insert components and patellar components), and all are provided sterilized by gamma irradiation or ethylene oxide.

The subject and predicate device K060515 have femoral components designed specifically for the right and left knees, in cruciate retaining (CR) designs, and provided in a range of sizes. Similarly, the subject device and the predicate device K060515 also include tibial trays that incorporate a similar stabilizing keel design, and both devices also include UHMWPE tibial inserts in CR designs for use with the corresponding femoral components.

The A200 Knee System and the predicate device K060515 components are similar in overall shape and design. The subject device and the predicate devices encompass a similar range of physical dimensions, including the AP and ML dimensions of the femoral and tibial tray components, the thickness of the tibial insert components, and the thickness and diameter of the patellar components. Constraint, contact area, and contact stress testing demonstrated the A200 Knee System to be substantially equivalent to K923277, K892800, K932837, and K935080.

The A200 Knee System and the predicate devices K103223 and K100048 include tibial inserts manufactured from UHMWPE containing alpha-tocopherol (vitamin E). Performance testing demonstrated that the wear rate of the A200 Knee System UHMWPE with vitamin E was substantially equivalent to the predicate devices K103223 and K100048.

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

Non-clinical testing data that was submitted, referenced, or relied upon to demonstrate substantial equivalence included: component testing (tibial tray fatigue, contact area, contact stress, constraint, and tibial insert-tray interlock strength); UHMWPE material characterization (density, swell ratio, oxidation index, trans-vinylene index, melting point, crystallinity, vitamin E content, free-radical content, assessment of consolidation by scanning electron microscopy, and analysis of extraction residues); UHMWPE mechanical testing (Izod impact resistance, tensile properties, compressive properties, small punch testing, fatigue crack propagation, and environmental stress cracking); and force-control wear testing according to the methods of ISO 14243-1 and ISO 14243-2.

The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, the A200 Knee System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principles,
- incorporates the same basic designs,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2013

Renovis Surgical Technologies, LLC
% Paxmed International, LLC
Kevin Thomas, Ph.D.
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K120038
Trade/Device Name: A200 Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: OIY, JWH
Dated: January 29, 2013
Received: January 30, 2013

Dear Dr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120038

Device Name: A200 Knee System

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1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
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3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is intended for cemented use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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